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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

REXINA MIZE, an individual; MINH NGUYEN, an individual;

Plaintiffs,

v.

MENTOR WORLDWIDE LLC; and DOES 1-100, inclusive,

Defendants.

CASE NO: **2:17-cv-01747 DMG(KSx)**

FIRST AMENDED COMPLAINT FOR DAMAGES

(1) NEGLIGENT AND NEGLIGENCE PER SE
(2) STRICT PRODUCTS LIABILITY- FAILURE TO WARN
(3) STRICT PRODUCTS LIABILITY- MANUFACTURING DEFECT
(4) BREACH OF IMPLIED WARRANTY
(5) LOSS OF CONSORTIUM

DEMAND FOR JURY TRIAL

Plaintiff REXINA MIZE, an individual, (hereinafter, "Plaintiff"), and Plaintiff MINH NGUYEN, an individual (hereinafter, "Spouse Plaintiff MINH NGUYEN" or "Plaintiff MINH NGUYEN") by and through their attorneys, based on information

and belief, and for causes of action against the Defendants, MENTOR WORLDWIDE LLC ("MENTOR"); and DOES 1 through 100, inclusive, (hereinafter collectively referred to as "Defendants") and each of them, hereby allege as follows:

I. INTRODUCTION

1. Plaintiff REXINA MIZE brings this action against Defendants, MENTOR WORLDWIDE LLC ("MENTOR"); and DOES 1 through 100, inclusive, (hereinafter collectively referred to as "Defendants"), and each of them, alleging the defective manufacturing of Mentor Worldwide LLC's MemoryGel® Silicone Breast Implants, the pervasive and continuous failure to comport with the Premarket Approval Application ("PMA") requirements imposed by the Food & Drug Administration ("FDA"), and failure to warn consumers of the known dangers.

2. Mentor Worldwide LLC touts itself as the global leader in aesthetic medicine, and the U.S. market leader in breast aesthetics. Founded in 1969, Mentor Corporation originally sold electronic laboratory instruments to measure activity within the nervous system. After introducing urethral catheters in the 1970s, they began delving into the plastic surgery field in the mid-1980s. Now, their breast implants have been used for millions of breast augmentation surgeries. Mentor Worldwide LLC is a leading supplier of medical products for the global aesthetic medicine market. The company develops, manufactures, and markets innovative, science-based products for aesthetics medical procedures.

3. Mentor is the only manufacturer whose breast implants are made in the United States of America. The company is focused on three main areas: breast, body, and facial aesthetics. For over 20 years, more than 5 million women have used Mentor breast implants, making Mentor one of the global leaders in breast aesthetics.

4. In November of 2006, Mentor received FDA approval for its MemoryGel® (silicone gel-filled) Breast Implants for use in breast augmentation and reconstruction surgery.

5. On January 23, 2009, Mentor was acquired by the Johnson & Johnson Family of Companies, and is part of its Global Surgery Group. Mentor sought to be the trusted global leader in aesthetic medicine among both consumers and professionals by providing a broad range of innovative, science and clinical-based solutions to maintain, enhance, and restore self-esteem and quality of life.

6. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic ("FDCA"). Breast implants were placed into Class II devices and reviewed through the premarket notification (510(k)) process. In 1988, in response to emerging safety concerns, the FDA re-classified breast implants to class III devices (requiring premarket approval, "PMA"), which was finalized in 1991 when the FDA published a final 515(b) regulation calling for new silicone gel-filled breast implant applications for premarket approval.

7. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, the FDA has determined that general and special controls alone are insufficient to ensure the safety and effectiveness of Class III devices. Therefore, these Class III devices require a PMA under § 515 of the FDCA in order to obtain marketing clearance for the manufacturer to bring the product to market.

8. In January 1992, the FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that manufacturers stop supplying them and surgeons stop implanting them while the FDA reviewed new safety and effectiveness information that had been submitted. In April 1992, the FDA determined that none of the PMAs submitted for Mentor's MemoryGel Silicone Gel Breast Implants contained sufficient data to support approval, and therefore, Mentor's MemoryGel Silicone Gel Breast Implants were no longer marketed in the U.S,

with the exception of use in reconstruction and revision patients. The FDA determined that access to silicone gel-filled breast implants for only reconstruction and revision patients could continue, but that implants used for these indications should be considered to be investigational devices, and women who received them should be followed through adjunct clinical studies.

9. According to the study entitled "Core Gel Study of the Safety and Effectiveness of Mentor Round Low Bleed Silicone Gel-filled Mammary Prostheses in Patients Who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction, or Revision," Clinical Trial Identifier No. NCT00753922, "In April 1992, the moratorium was lifted but only for reconstruction and revision patients. Every patient implanted had to be part of an adjunct study, and had to be offered participation in a registry of gel-filled breast implant patients. In order to be implanted with gel-filled implants for *augmentation*, women had to be enrolled in a core clinical study." (emphasis added). ***See Exhibit A,*** Core Get Study, pg. 3.

10. In December 2003, Mentor Worldwide LLC ("Mentor") submitted a PMA for its MemoryGel Silicone Gel Breast Implants. On November 17, 2006, the FDA approved Mentor's PMA, reference number P030053. ***See Exhibit B,*** Approval Letter.

11. This was the first time silicone gel-filled breast implants were available for augmentation, in addition to reconstruction and revision, since the moratorium was established in 1992. As conditions of approval, Mentor was required to conduct six post-approval studies to further characterize the safety and effectiveness of their MemoryGel Silicone Gel Breast Implants and to answer scientific questions that the premarket clinical trials were not designed to answer. The following post-approval study requirements were listed by the FDA in the PMA granting Mentor's MemoryGel™ Silicone Gel-Filled Breast Implants:

1) Core postapproval study (core study)- To assess long-term clinical performance of breast implants in women that enrolled in studies to

support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.

2) Large postapproval study (large study)- To assess long-term outcomes and identify rare adverse events by enrolling more than 40,000 silicone gel-filled breast implant patients, following them for 10-years.
3) Device failure studies (failure study)- To further characterize the modes and causes of failure of explanted devices over a 10-year period.
4) Focus group study- To improve the format and content of the patient labeling.
5) Informed decision process - To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.
6) Mentor adjunct study - To provide performance and safety information about silicone gel-filled breast implants provided to U.S. women from 1992-2006, prior to approval, when implants could only be used for reconstruction and replacement of existing implants.

12. Mentor failed to report adverse events from the six new or ongoing studies commissioned as part of the implant's PMA approval, which would have led to reports suggesting the device's contribution to serious injury.

13. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer. The manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post market complaints and data.

14. To fulfill this essential responsibility, a manufacturer must vigilantly monitor all reasonably available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the U.S. Food and Drug

Administration ("FDA"), the healthcare community and to consumers. The manufacturer also must carefully monitor its own manufacturing operations and quality controls to ensure that the device uniformly conforms to the manufacturer's approved design, as well as its representations and warranties and with specifications of approval.

15. When monitoring and reporting adverse events as required by both federal regulations and California law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to the manufacturer and the medical community that a public safety problem exists. If a manufacturer waits to report post-market information, even for a few weeks or months, that bottleneck could mean that researchers, regulatory bodies, and the medical community are years behind in identifying a public safety issue associated with the device. In the meantime, more patients are harmed by using the product without understanding its true risks. This is why a manufacturer must not only completely and accurately monitor, investigate and report post-market experience, but it must also report the data as soon as it is received.

16. Defendants failed to fulfill their post-market responsibilities to adequately conduct, monitor, follow-up, and warn about serious health risks regarding their MemoryGel Silicone Gel Breast Implants, which were conditions of approval specified by the FDA. *See Exhibit B*, pg. 2-4.

II. PARTIES, JURISDICTION AND VENUE

17. At all times relevant hereto, Plaintiff REXINA MIZE is and was a citizen and resident of Los Angeles County, California.

18. At all times relevant hereto, Spouse Plaintiff MINH NGUYEN is married to, and the husband of, Plaintiff REXINA MIZE, and is and was a citizen and resident of Los Angeles County, California.

19. Mentor Corporation was a corporation located in Minneapolis, Minnesota.

Defendant Mentor Worldwide LLC, upon information and belief, is the successor in interest of Mentor Corporation.

20. Defendant MENTOR WORLDWIDE LLC is a limited liability company, and is deemed a citizen of the state of its members. It is incorporated under the laws of the State of Delaware, with its principal place of business located at 201 Mentor Drive, Santa Barbara, California, 93111, and its headquarters located at 33 Technology Drive, Irvine, California, 92618.

21. Defendant Mentor moved its headquarters to Santa Barbara, California in 1985.

22. Defendant Mentor is a wholly-owned subsidiary of Johnson & Johnson. Johnson & Johnson, through its subsidiary Ethicon, Inc., acquired Mentor Corporation. Mentor Texas, Inc. is a wholly owned subsidiary of the Mentor Corporation, located at 201 Mentor Drive, Santa Barbara, California 93111.

23. The Johnson & Johnson corporate family structure includes a multitude of wholly-owned subsidiaries and affiliated companies all over the world, including Mentor Worldwide, LLC, which is based and operates out of California.

24. ETHICON, INC. is a subsidiary of Johnson & Johnson. Under the terms of the acquisition of Defendant Mentor, Defendant Mentor was expected to operate as a stand-alone business unit reporting through ETHICON, Inc., a Johnson & Johnson company, and leading provider of suture, mesh and other products for a wide range of surgical procedures.

25. The true names and/or capacities, whether individual, corporate, associate or otherwise of Defendants DOES 1 through 100, inclusive, are unknown to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and believe, and thereupon allege, that each of the Defendants fictitiously named herein as a DOE is legally responsible, negligently or in some other actionable manner, for the events and happenings hereinafter referred to, and thereby proximately caused the injuries and damages to Plaintiffs as hereinafter alleged.

Plaintiffs will seek leave of court to amend this Complaint to insert the true names and/or capacities of such fictitiously named Defendants when the same have been ascertained.

26. Hereinafter, the aforementioned Defendants may collectively be referred to as "Defendants."

27. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

28. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

29. At all relevant times, Defendants acted in concert with one another in the State of California to fraudulently convey false and misleading information concerning Mentor MemoryGel Silicone Gel Breast Implants (the "product"), and to conceal the risks of serious adverse events associated with Mentor MemoryGel Silicone Gel Breast Implants from the public, Plaintiffs, physicians, and other healthcare providers. These concerted efforts resulted in significant harm to Plaintiffs. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiffs would not have been implanted with Mentor MemoryGel Silicone Gel Breast Implants and would not have suffered severe injuries.

30. This Court has personal jurisdiction over Defendants. Defendants are and were at all relevant times residents of and/or authorized to conduct business in the State of California and Defendants conducted such business within the State including the performance of acts that caused or contributed to the harm giving rise to this action.

31. At all times material hereto, Defendants maintained systematic and continuous contacts in this judicial district, regularly transacted business within this judicial district, employed numerous individuals in this district and regularly availed

themselves of the benefits of this judicial district. Defendants received substantial financial benefit and profits as a result of the designing, formulating, testing, packaging, labeling, producing, creating, constructing, making, assembling, advertising, clinical testing, marketing, promoting, distributing, manufacturing, and selling the product in this district and throughout the United States.

32. At all times material hereto, the action arises from obligations that arise out of, or are connected with, Defendants' activities within the State of California.

33. Plaintiff's claims arise out of and/or are related to Defendants' California-related forum activities. Plaintiffs are informed and believe and on that basis allege that Defendants have purposefully directed their activities at this forum State, and the exercise of jurisdiction is reasonable and would not offend the traditional notions of fair play and substantial justice. Plaintiffs are informed and believe and on that basis allege that Defendants have purposefully availed themselves of the privileges and benefits of conducting activities with the forum State, and have invoked the benefits and protections of its laws.

34. This court has subject matter jurisdiction based on diversity of the parties and the amount in controversy exceeds $75,000 as required under 28 U.S.C. § 1331.

35. Venue is appropriate in the Central District of California pursuant to 28 U.S.C. § 1391(a), in that Defendant Mentor has its principle place of business in California and a substantial part of the events giving rise to this action occurred in this District, as well as the implantation, injuries, and explantation of the product.

III. DELAYED DISCOVERY

36. Plaintiff exercised reasonable diligence in investigating her injuries, and could not have discovered that her injuries were caused by the product at an earlier time. The discovery rule applies to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence, should have known of the existence of her claims against all Defendants.

37. The nature of Plaintiffs injuries and subsequent damages, and their causal

relationship to the product were not, and could not, have been discovered through reasonable care and diligence.

38. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, the cause of her injuries caused by the product, or the tortious nature of the conduct causing those injuries, until less than the applicable limitations period prior to the filing of this action.

39. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her healthcare providers the true and significant risks associated with the product.

40. Further, Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from, and misrepresented to, Plaintiff the connection between the injuries sustained and the Defendants' tortious conduct.

IV. FACTUAL ALLEGATIONS: MEMORYGEL® SILICONE BREAST IMPLANTS

A. Regulatory History of Silicone Breast Implants in The U.S.

YEAR	EVENT
1960s	The first silicone breast implants are developed by two plastic surgeons.
1976	Congress passed the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. Breast implants were placed into Class II and reviewed through the premarket notification [510(k)] process.
1982- January	FDA proposes to classify silicone breast implants into Class III category which would require manufacturers to prove their safety and efficacy in order to keep them on the market.
1988- June	In response to emerging safety concerns, the FDA re-classified breast implants to class III devices (requiring premarket approval). However, in accordance with the law, they continued to be reviewed through the 510(k) process until the FDA issued a rule calling for submission of premarket approval applications (PMAs).
1991-April	The FDA issued a final rule calling for submission of PMAs for silicone gel-filled breast implants.
1991- September	The FDA concluded that the silicone breast implant manufacturers' safety data did not prove the devices are safe- or harmful. Manufacturers are told to submit further data.

1991-November	The FDA held an Advisory Panel meeting to discuss several PMAs for silicone gel-filled breast implants. While the panel concluded that the manufacturers had failed to provide adequate safety and effectiveness data for their implants, they unanimously recommended that the FDA permit the implants to remain on the market.
1992-January	The FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that manufacturers stop supplying them and surgeons stop implanting them, while the FDA reviewed new safety and effectiveness information that had been submitted.
1992-February	Based on new information, the FDA held a second Panel meeting to re-evaluate the safety of silicone gel-filled breast implants. This time the panel recommended that silicone gel-filled breast implants be removed from the market pending further evaluation of the new data.
1992-April	The FDA commisionner lifted the moratorium on silicone breast implants. The only women allowed to receive implant surgery are those undergoing breast reconstruction. All of the implant recipients must become part of a scientific protocol. The FDA concluded: •None of the PMAs submitted for silicone gel-filled breast implants contained sufficient data to support approval. •Access to silicone gel-filled breast implants should continue for patients undergoing breast reconstruction or for replacement of existing silicone gel-filled breast implants (revision). Implants used for these indications should be considered to be investigational devices, and women who received them should be followed through adjunct clinical studies.
1992-July	The FDA approved Mentor's Adjunct Study protocol for its silicone gel-filled breast implants for reconstruction and revision patients only.
1999	Silicone gel-filled implants remain off the market in the U.S. pending manufacturer safety studies.
2000-Auguest	The FDA approved Mentor's IDE study (i.e., Core Study) for its silicone gel-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites. This is the Core Study for submission P030053.
2003-December	Mentor submitted a PMA (P030053) for its silicone gel-filled breast implants.
2005-April	The FDA held an Advisory Panel meeting to review Allergan's updated PMA and Mentor's PMA. In a 5 to 4 vote, the panel did not recommend approval of Allergan's PMA (due to a concern with one style in the application). In a 7 to 2 vote, the panel recommended approvable with conditions for Mentor's PMA. The panel recommended that FDA require conditions including a minimum age requirement for augmentation and Post-Approval Studies.

2006-November	The FDA approved Allergan and Mentor's PMAs for silicone gel-filled breast implants. This was the first time silicone gel-filled breast implants were available for augmentation, in addition to reconstruction and revision, since the moratorium was established in 1992. As conditions of approval, each manufacturer was required to conduct 6 post-approval studies to further characterize the safety and effectiveness of their silicone gel-filled breast implants and to answer scientific questions that the premarket clinical trials were not designed to answer.

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2011-January	The FDA issued a Safety Communication on anaplastic large cell lymphoma (ALCL) in women with breast implants. Based on a review of the scientific literature, the FDA believes that women with breast implants may have a very small but increased risk of developing this disease in the scar capsule adjacent to the implant.
2011-June	The FDA issued an Update on the Safety of Silicone Gel-Filled Breast Implants. It included preliminary results of the post approval studies Allergan and Mentor were required to perform as conditions of their silicone gel-filled breast implant 2006 approval.
2011-August	The FDA held an Advisory Panel meeting to discuss and receive recommendations on postmarketing issues related to silicone gel-filled breast implants. Also discussed at this meeting were innovative methodological approaches to postmarket studies regarding silicone gel breast implants, as well as key long-term safety issues associated with silicone gel breast implants in the real-world setting.

2013-June	The FDA approved Mentor's PMA for a silicone gel-filled breast implant that uses a more cohesive silicone gel, compared to their previously approved breast implant. As a condition of approval, the manufacturer was required to conduct a series of post-approval studies to further characterize the safety and effectiveness of their breast implant and to answer scientific questions that the premarket clinical trial was not designed to answer.

B. Background About Silicone Breast Implants

41. Silicone is the name given to a family of synthetic polymers composed of a repeating Si-O backbone and carbon-linked side groups. Si-C bonds do not exist in nature, but can be formed under appropriate manufacturing conditions.

42. Silicon was discovered by Jöns Jacob Berzelius, a Swedish chemist, in 1824 by heating chips of potassium in a silica container and then carefully washing away the residual by-products. Silicon is the seventh most abundant element in the universe and the second most abundant element in the earth's crust. Today, silicon is produced by heating sand (SiO_2) with carbon to temperatures approaching 2200°C.

43. It is most widely distributed in dusts, sands, planetoids, and planets as various forms of silicon dioxide (silica) or silicates. Over 90% of the Earth's crust is composed of silicate minerals, making silicon the second most abundant element in the Earth's crust after oxygen.

44. A breast implant is a prosthesis product used to change the size, shape, and contour of a woman’s breast. There are three general types of breast implant devices, defined by their filler material: saline solution, silicone gel, and composite filler.

45. Generally, there are five generations of silicone breast implants Upon information and belief, the various generations exemplified the following characteristics:

- **First Generation** (1962-1970)
  - Thick, two-piece shell
    Smooth surface with Dacron fixation patches
    Anatomically shaped (teardrop)
    Viscous silicone gel
    Featured teardrop-shaped sac

- **Second Generation** (1970-1982)
  - Thin, slightly permeable shell
    Smooth surface (no Dacron patches)
    Less viscous silicone gel
- **Third Generation** (1982-1992)
  - Thick, strong, low-bleed shell
    Smooth surface
    Round shape
    More viscous silicone gel
- **Fourth Generation** (1993-present)
  - Thick, strong, low-bleed shell
    Smooth and textured surfaces
    Round and anatomically shaped
    More viscous (cohesive) silicone gel
    Elastomer-coated implant shells
- **Fifth Generation** (1993-present)
  - Thick, strong, low-bleed shell
    Smooth and textured surfaces
    Round and diverse anatomical shapes
    Enhanced cohesive and form-stable silicone gel

46. Silicone gel-filled breast implants have a silicone outer shell that is filled with silicone gel. They come in various sizes and can have either a smooth or textured shell. Silicone gel-filled breast implants are approved for breast augmentation in women age 22 or older and for breast reconstruction in women of any age.

47. While silicone breast implants have been in use since the 1960s, it was not until 1976 that legislation was passed giving the FDA responsibility to oversee the safety of medical devices. In 1982, the FDA proposed that the manufacturers of implants provide additional evidence on the safety of breast implants. In 1988, the FDA mandated the manufacturers provide such evidence. This ruling was not enforced until 1991. The head of the FDA asked for a voluntary moratorium on the use of silicone gel-filled implants. He banned their use except in clinical trials of breast reconstruction after cancer surgery. He stated that the ban was implemented not because gel-filled implants had been shown to be unsafe, but rather, because the manufacturers had not provided adequate date proving their safety.

48. The FDA, after the enactment of the MDA, allowed the use of silicone-filled breast implants as long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. §360e(d)(2). In 1988, in response to emerging safety concerns, the FDA re-classified breast implants to class III devices (requiring premarket approval), which was finalized in 1991 when the FDA published a formal 515(b) regulation allowing for PMAs for silicone gel-filled breast implants.

49. In 1992, the FDA determined that there was insufficient data for approval, and Mentor's MemoryGel Silicone Gel Breast Implants were no longer marketed in the U.S., with the exception of use in reconstruction and revision patients.

50. Upon information and belief, approximately 5 to 10 million women worldwide have breast implants. According to the American Society of Plastic Surgeons National Clearinghouse of Plastic Surgery Procedural Statistics, there were 296,203 breast augmentation procedures and 93,083 breast reconstruction procedures performed in the United States in 2010.

C. Pre-Market Approval

51. Pre-market Approval ("PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. See 21 U.S.C. § 515(b); 21 CFR § 814.3(e).

52. A PMA application must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement application must provide:

a. proposed indications for use;

b. device description including the manufacturing process;

c. any marketing history;

d. summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk considerations);

e. each of the functional components or ingredients of the device;

f. methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. any other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should reasonably be known to the manufacturer from any source, including information derived from investigations other than those proposed in the application and from commercial marketing experience.

53. According to the FDA, a Class III device that fails to meet the Conditional Premarket Approval ("CPMA") requirements after marketing is considered to be adulterated under § 501(f) of the Federal Food, Drug and Cosmetic Act ("FDCA") and cannot continue to be marketed.

54. Defendants are required to comply with all FDA post –marketing requirements for Class III medical devices. Approval of a device through the PMA process signals the beginning, not the end, of a device manufacturers duties to patients under both federal regulations and established California law.

55. Defendants' post-approval obligations under federal law included, but are not limited to:

a. report to the FDA information suggesting that one of the Manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, 21 CFR §§ 803.50 et seq.;

b. monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;

c. submit a PMA Supplement for any change in Manufacturing Site, 21 CFR §§ 814.39 et seq.;

d. establish and maintain quality system requirements to ensure that quality requirements are met, 21 CFR § 820.20 et seq.;

e. establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, 21 CFR §§ 820.30 et seq.;

f. document all Corrective Action and Preventative Actions taken by the Manufacturer to address non-conformance and other internal quality control issues, 21 CFR §§ 820.100 et seq.;

g. establish internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq. and §§ 820.20 et seq.;

h. establish Quality Management System (QMS) procedures to assess potential causes of non-conforming products and other quality problems, 21 CFR §§820.70 et seq. and 21 CFR §§ 820.90 et seq.;

i. report on Post Approval Studies in a timely fashion, 21 CFR §§ 814.80 et seq.; and

j. advertise the device accurately and truthfully, 21 CFR §§ 801 et seq.

56. Had Defendants fulfilled these obligations, which federal and state law required them to do, Plaintiff's injuries would not have occurred. Defendants failed to do so.

57. Under state law, including California law, Defendants had a duty to exercise reasonable care in adequately warning Plaintiff and/or Plaintiff's physician about the dangers of Mentor MemoryGel silicone breast implants that were known or knowable to Defendants at the time of distribution. Under both federal and state law, Defendants also have a post-market duty to monitor and report adverse events and risks associated with the device. Despite having knowledge and possession of evidence that showed the use of Mentor MemoryGel silicone breast implants were dangerous and likely to place consumers' health at serious risk, Defendants failed to

disclose and warn of the health hazards and risks associated with the product. Instead, Defendants marketed, advertised, and promoted the product while failing to monitor, warn, or otherwise ensure the safety and efficacy of its users in violation of state law, including California law, and FDA regulations.

58. The FDA's initial approval of a device label amounts to a finding by the FDA that the label is adequate for purposes of gaining initial approval to market the device. It does not represent a finding by the FDA that the label can never be deemed inadequate after approval as new safety information from the real world experience with the device becomes available to the manufacturer. Sound reasons support these principles: there are products, such as Mentor MemoryGel silicone breast implants, for which evidence of the device's defects comes to light only after the device is used in a real world setting.

59. After Mentor MemoryGel silicone breast implants received pre-market approval, Defendants were at all times responsible for maintaining the labeling Mentor MemoryGel silicone breast implants in light of the most current risk information obtained from the real world clinical experience with the device. There is no federal requirement that a manufacturer maintain its original warning language in the face of new safety information. Nor does federal law give device manufacturers a right to market their device using the label originally approved by the FDA when new post-market information bearing on the safety of the device comes to light. To the contrary, the FDCA required Defendants not to sell a device that was accompanied by an inadequate warning or had a label that was false or misleading in any respect, 21 U.S.C. § 352(a), (f)(2), because such a deficient warning rendered the device "misbranded" under 21 U.S.C. § 331, as well as the Sherman Food, Drug, and Cosmetic Laws. West's Ann. Cal. Health & Safety Code § 111330.

60. Defendants were at all times responsible for maintaining the labeling of the product, and had the ability under federal law, and the duty under state and federal law, to directly warn healthcare providers and consumers unilaterally updating the

labeling of Mentor MemoryGel silicone breast implants to reflect newly acquired safety information without advance approval by the FDA.. Accordingly, Defendants had the ability to file a "Special PMA Supplement – Changes Being Effected" ("CBE") which allows Defendants to unilaterally update the labeling to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d). These changes include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

61. Defendants breached their duties under federal law and state law, including California law, to maintain labeling that: (a) added instructions for use that would enhance the safe use of the device; and (b) added descriptions of adverse events to ensure that the labeling was not false or misleading.

62. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a). Specifically, 21 C.F.R. § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury, or has malfunctioned and the malfunction would be likely to contribute to a serious injury if

it were to recur.

63. The FDA publishes the adverse events and MDRs in a public, searchable Internet database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.

D. Mentor MemoryGel Silicone Breast Implants & PMA Approval

64. Mentor MemoryGel Breast Implants are filled with Mentor's proprietary cohesive gel, and contain the latest generation of silicone. They are prefilled with Mentor's uniquely formulated silicone gel. This gel is not like a liquid or a semi-liquid. Instead, it is a cohesive gel that closely resembles breast tissue.

65. Upon information and belief, at all relevant times, Mentor designed, manufactured, tested, and distributed Mentor breast implants, including the Mentor MemoryGel Silicone Gel Breast Implants.

66. Defendant Mentor filed a premarket approval application on or about December 12, 2003.

67. On November 17, 2006, the FDA approved Mentor's PMA for MemoryGel Silicone Gel-Filled Breast Implants, P030053, which allowed Mentor to market the product. ***See Exhibit B,*** Approval Letter.

68. As conditions of approval, Mentor was required to conduct six post-approval studies to further characterize the safety and effectiveness of their MemoryGel Silicone Gel Breast Implants and to answer long term questions that the premarket clinical trials were not designed to answer. The FDA required Mentor to (1) Continue and complete their core post-approval study, (2) Conduct a large post-approval study to assess long-term outcomes and identify rare adverse events by enrolling 41,900 silicone gel-filled breast implant patients and 1,000 saline-filled breast implant patients and follow them for 10 years, (3) Conduct a device-failure study in concert with their large post-approval study to further identify the modes and causes of failure of explanted devices over the 10-year period, (4) Complete a focus-

group study to evaluate how easily patients understand the information in the informed decision brochure about the risks associated with the use of silicone breast implants, (5) Complete an informed decision study to monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants, and (6) Complete the Mentor adjunct study, which was in place after 1992, when the FDA allowed Mentor to market silicone gel-filled breast implants for reconstruction after mastectomy, correction of congenital deformities, or replacement of existing implants. Women who received silicone gel-filled breast implants for these purposes were enrolled in Adjunct Studies so that data about device performance and safety could be collected. Participant enrollment began in 1992 for Mentor. As a condition of approval of silicone gel-filled breast implants in 2006, Mentor was required to close enrollment of new patients into the Adjunct Studies but continue to follow existing participants through their 5-year post-implant evaluations.

1) **Core Post Approval Study**

69. As one of the conditions of approval, the FDA specifically required Mentor to continue their Core Study, which had been underway since September 2000 and published in Mentor's PMA. ***See Exhibit C,*** Core Study. There were 1008 patients enrolled in that study. Mentor was to continue the study until all patients had completed their 10-year evaluation in order to assess the long-term clinical performance of their product. There were to be 11 follow-up visits, at 6 months post-operation, and annually 1 year to 10 years after surgery. Mentor was required to collect data via annual physician follow-up evaluations. The primary changes to the protocol from premarket to post approval were that all non-MRI patients should have an MRI at years 6, 8, and 10 and that all patients who were explanted without replacement were to be evaluated through 10 years. Mentor was also required to update their patient and physician labeling to reflect the results of the 5 and 10-year Core Study findings and to report to the FDA significant new information regardless of when the information became available.

70. According to the FDA website, the core post-approval study follow-up rates at 9 years post-implant were only 59 percent.[1] However, the core post-approval study page states that the follow-up rate at 10 years post-implant was 62 percent. *See Exhibit C,* pg. 1. Furthermore, the FDA requirements specifically mandated evaluation through 10 years, but the core post-approval study report schedule illustrates that reporting was only done for 6 years. *See Exhibit C,* pg. 2. The lack of a sufficient statistical sample, due to the low follow-up rate, as well as the inconsistent data and the failure to conduct the full study hampered Mentor's ability to alter the labeling and defeated the purpose of the study in assessing the 10 year long-term clinical performance of the product.

71. The reported findings of this study lack statistical reliability, and did so in the sub-groups (cohorts): primary augmentation, revision augmentation, primary construction, and revision reconstruction.

72. In the primary augmentation cohort, Mentor only reported the reasons for reoperation in 36% of the sample. Mentor failed to disclose to the FDA the reasons why only about one-third of the sample were included in this aspect of the study.

73. In the revision augmentation cohort, reoperation rate was 43%. Mentor reported the most common reason for reoperation, which was capsular contraction, at 30.4%. Mentor failed to disclose other reasons why women in this category needed reoperation.

74. In the primary construction cohort, Mentor reported reoperation rates at 49%. Mentor reported that of that group, 16.6 % needed reoperation because of asymmetry, 14% for capsular contraction, 12.7% for rupture, and 10.8% for breast mass. Fully 47% of women in this category needed reoperation for which Mentor failed to document or explain the reasons.

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[1] https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm337827.htm, last checked April 25, 2017.

75. In the revision reconstruction cohort, reoperation was performed on 50.7% of the women surveyed. The most frequently reported reasons were capsular contraction and breast mass totaling 36.2% of reoperations, leaving the remainder of reasons for reoperation unreported. Other reported reasons, including connective tissue and neurologic disorders and gel bleed were downplayed even though they were significant given the small sample studied.

2) **Large Post-Approval Study**

76. The FDA's approval also required Mentor to conduct a 10-year large post approval study, consistent with a protocol submitted to the FDA by Mentor on September 26, 2006. ***See Exhibit D,*** Large Cohort Study.

77. That protocol required patient enrollment within 90 days of issuance of the PMA. The Large Post-Approval Study was to be a separate study from the Core Study and was to include 41,911 Mentor silicone gel patients and 1,017 saline-filled breast implant patients as the control group. The purpose of this study was to address specific issues for which the Core Study was not designed to fully answer, including a real-world assessment long-term local complications, such as connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms; offspring, reproductive, and lactation issues; cancer rates, suicide, mammography issues, rupture results, and MRI compliance. The data was to be collected through annual patient questionnaires, either completed via the internet, mail, or telephone. The study also required physician evaluations at years 1, 4-6, 9 and 10 to collect data on complications. Mentor was required to update their patient and physician labeling to reflect the 5 and 10-year study findings, as well as at any other time if necessary to report significantly new information from the study.

78. At the outset, the actual number of MemoryGel enrolled participants was approximately 41,452, almost 500 patients fewer than the PMA requirements. Mentor initiated patient enrollment in February 2007 and closed enrollment in July 2009, with a total of 41,975 silicone gel filled breast implant participants, however Mentor's data

included only 41,419 patients who met the original enrollment criteria because over 500 were under the age of 22. *See Exhibit J.* The FDA asked Mentor provide data and analyses on these younger women in future analyses.

79. Enrollment by indication was 26,173 primary augmentation participants, 8,382 revision-augmentation participants, 5,023 primary reconstruction participants, 1,761 revision-reconstruction participants, and 113 participants did not provide important information. By year 7, the overall follow-up rate was 20.1% (approximately 8,331 participants out of 41,452), leaving 79.9% of the desired statistics unavailable for evaluation.

80. This was a study of significant importance required by the FDA for post market approval. The study was designed to address a critical spectrum of health issues for women with breast implants. Mentor did not comply with the required data collection. With nearly an 80% dropout rate, the study failed to collect data to demonstrate that use of the Mentor silicone gel implants was safe. The inadequate results are even more disconcerting because the data collection was designed to examine reasons for reoperation-previously unevaluated-including MRI results, and rheumatologic or neurological symptoms. The lack of participation and reliable results from this study show that Mentor has failed to comply with FDA requirements. Mentor did not follow through with data collection. The Year 1 follow-up rate of surgeon visit for MemoryGel participants was 22.8%, leaving nearly 80% unaccounted for; the Year 1, 2, and 3 follow-up rates of MemoryGel patient questionnaires were 21.4%, 24.3%, and 23.0%, respectively, leaving nearly 80% unaccounted for. These follow-up rates were too low for Mentor to provide meaningful safety information. At Year 7, the overall follow-up rate was 20.1%, leaving 79.9% of participants unaccounted for and did not have follow-ups for data collection. No follow-up rates were provided for the 10-year data collection.

3) **Device Failure Study**

81. In order to ascertain the reasons for and frequency of device failure, the FDA specifically required that "Mentor must continue preclinical studies to characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large postapproval study." ***See Exhibit E,*** Device Failure Study. This study was to address the following specific issues: "(1) further evaluation of iatrogenic failures to address issues raised by the April 2005 Panel, (2) the characterization of when surgical instrument damage occurs, (3) further evaluation and characterization of failures due to localized shell stress, and (4) any correlation between surgical factors (e.g., incision size) and device rupture." Mentor was also required to update their patient and physician labeling to reflect any relevant findings from this study.

82. The study design involved two components: 1) the collection of implant/surgery information and clinical data at the time of explantation, and 2) visual inspection and physical testing of the explanted devices. No study population was stated, and there was no patient follow-up.

83. As of August 31, 2009, 97 core gel devices had been explanted and returned for evaluation. *See Exhibit E.* However, the post-approval Device Failure study goes on to state that for MemoryGel post-approval devices, a total of 1,545 implants (1,379 smooth and 166 textured) were retrieved *worldwide,* and not just within the United States, from November 17, 2006 through August 31, 2009. Of the 1,545 retrieved devices, 664 were from the United States and 881, or 57%, were outside the United States. *Only 62 retrieved devices, or 4%, were associated with the PAS (post-approval study) patients*, and 1,483 devices, or 95%, were associated with non-PAS patients or international patients. *See Exhibit E,* pg. 1.

84. Mentor's Device Failure post-approval study failed to contain an adequate sample size to provide meaningful data.

85. Mentor's Device Failure post-approval study report of summary findings to the FDA did not list results of the data findings (no clinical data and no visual

inspection data), did not list safety findings, did not list any recommendations or summary of safety and data or follow-up on the data, and did not list any changes to labeling, all in violation of this condition established in the approval of Mentor's PMA.

86. Overall, Mentor blatantly failed to meet the FDA's requirements. Mentor merely filed a report with minimal information just to show that they were following reporting protocol.

4) **Focus Group Study**

87. This condition required Mentor to complete a focus group study of the augmentation and reconstruction patient groups. ***See Exhibit F,*** Focus Group Study. An independent group was to obtain responses from patients on the adequacy of the format and content of the approved labeling. Upon completion of the focus group study, Mentor was to provide a report of the findings and a revised patient and physician labeling based on those findings.

88. Mentor used only 35 women to evaluate how patients understood the safety and labeling brochures. The study used two methods of data collection-discussion groups and self-administered surveys. Endpoints included participants' reactions to the layout and format of the brochures, content order, illustrations, and tables. Data was to be collected on their comprehension and perceived relevance of the content. Some respondents concluded that the true purpose of the brochure was to protect Mentor, rather than inform patients about the risks of breast implant surgery. Respondents reported that the information on the labeling did not help them understand the risks and complications associated with breast implants. They also reported that most of the information did not help them weigh the relative importance of risks and complications associated with breast implants. Respondents also felt the brochure fell short of providing information on the benefits of breast implants and did not acknowledge the deeply personal benefits of body image and self-esteem, especially for women who lose their breast to cancer.

89. The recommendations for labeling changes included adding information clearly describing differences between restoration, replacement, reconstruction, and revision early in the main body of the brochure; adding information on potential complications based on the likelihood of occurrence; providing more information about benefits; and providing more qualitative information to help women make more informed decisions.

90. Despite the long list of recommendations for labeling changes, no further tests were done. Moreover, the small number of women studied and the blatant disregard for the recommendations for labeling exemplifies that the PMA requirements were not met by Mentor.

5) **Informed Decision Study**

91. The Informed Decision Study required Mentor to distribute their approved patient labeling to all physicians intending to use the silicone gel products. ***See Exhibit G,*** Informed Decision Study. It was designed as a random survey of 50 physicians on an annual basis to determine the success of the informed decision process provided to women who seek breast implant surgery. Both the physician and the patient were intended to sign designated sections in order to best assure that the patient had obtained the labeling in sufficient time prior to surgery to read it and understand the risks and other information associated with the Mentor device.

92. Mentor was to conduct the survey randomly, selecting 50 physicians on an annual basis, collect the results and provide a summary of the findings to the FDA under the condition the FDA was to evaluate the findings and advise Mentor if and when the annual survey was no longer necessary. In addition, Mentor was to provide training on this process as part of their physician training program.

93. The study protocol parameters indicated there were no follow-up visits in the study.

94. The summary of findings filed by mentor did not list the sample size of patients enrolled. It only provided insight for one year (2011) and reported that 54

surveys were returned by 50 physicians and did not list what went into the survey or which points were assessed. Mentor provided minimal information on the outcome.

6) **Mentor Adjunct Study**

95. The final condition imposed by the FDA required Mentor to continue the adjunct study. ***See Exhibit H,*** Adjunct Study. This study was originally designed to serve a public health need for reconstruction and revision patients, but because that need was no longer an issue (because of the PMA), Mentor was required to: (1) cease new patient enrollment into the study, and (2) continue to follow-up on all currently-enrolled Mentor Adjunct Study patients through 5 years. The data from the follow-up study was to be reported as part of the annual reports required by the PMA.

96. The Adjunct Study was designed to follow-up with patients post-operatively at years 1, 3, and 5 to assess satisfaction and occurrence of local complications. The study was to gather data regarding short-term and local (tissue) implant complications. Clinical endpoints for years 1, 3, and 5 follow-ups included infection, seromas, ruptures, and capsular contracture; for years 3 and 5 follow-ups were rheumatological/immunologic symptoms.

97. While a large number of patients were enrolled in the Adjunct Study, designed to address the public health needs of reconstruction and revision patients before device approval and to gather safety data regarding short-term post-implant complications, the overall patient follow-up rates at Year 1 was 44%, Year 3 was 24.7%, and Year 5 was 13.8%, meaning that at Year 5, 86.2% of the patients were not included in the follow-up data. Mentor reported to the FDA that "poor patient compliance significantly limited interpretation of the available safety results."

E. Defendant Mentor Violated the Conditions of the Product's PMA

98. Mentor's duty to the scientific community and women who have undergone augmentation for any reason - at the insistence of the FDA - was to design an effective study. It was Mentor's obligation to design and execute a study where women were able to access internet forms that are easily understood and provide a

working forum to report their experience with implants. Mentor intentionally and systematically failed to make this happen which is a violation of the FDA's conditions for approval. *See Exhibit B.* Data collection was sparse and potential serious side effects and harmful complications were downplayed and under-reported due to inadequate sample size and low follow-up rates.

99. All six of these studies were supposed to support long-term safety. The poor follow-up rates and inadequate data confirm Mentor's intentional and systematic failure to follow FDA requirements for post-approval studies.

100. For instance, halfway through the ten-year prospective post-marketing studies mandated by the FDA, well over 50% of the 80,000 women in the study groups were dropped or otherwise eliminated from the studies. Of the patients who were accounted for, significant numbers reported systemic ailments which can only be attributed to gel bleed introducing known toxins including silicone, heavy metals and chemicals into their bodies. Mentor was aware, or should have been aware that the gel contained chemicals and metals toxic to the human body but failed to adequately report that to the FDA and warn their patients of their dangerous consequences.

101. Upon information and belief, a Mentor chemist of 15 years reported to the FDA that the implants are more likely to break than the company reported. It has also been reported that the silicone is more likely to leak, even when the implants are intact, and that platinum used in the implants is more dangerous than reported. Mentor knew of these risks associated with implants, but covered them up by terminating studies, sponsoring only self-serving research they could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

F. Defendants' Actions Violated Federal and State Regulations Governing the Device and also Violated California State Law

102. Defendants have a duty under California law to exercise reasonable care in warning Plaintiffs and/or Plaintiffs' physicians about the dangers of products that

were known or knowable to Defendants at the time of distribution. Defendants here failed to do so.

103. Defendants also have a duty under California law to law to exercise reasonable care in the manufacture, development, design, marketing, labeling, distributing, and sale of the product. Defendants here failed to do so.

104. Defendants also had the obligations and the ability under federal regulations to maintain labeling that provides adequate warnings about risks and instructions for use; to ensure that the product was manufactured utilizing Good Manufacturing Practices; to conduct prompt, accurate and thorough post-market surveillance; to take action to ensure that the device can be used safely in accordance with the instructions; to maintain quality controls to adequately address, investigate, and assess the product's performance post-market; and to ensure that any labeling, warranties, or representations Defendants made were not false or misleading in any respect. Defendants conduct here failed to meet these federal obligations and also violated California law.

105. Mentor, as the device manufacturer, failed to comply with the post-market conditions imposed on it by the FDA to continue to monitor the use of its product to determine the safety and effectiveness, and to report any findings of adverse health consequences that may be attributable to the product to the FDA.

106. Mentor failed to report adverse events from the six new or ongoing studies commissioned as part of the product's PMA approval, which would have led to adverse event reports revealing the product's contribution to serious injury. This demonstrates a continued violation of the requirements issued by the FDA.

107. Defendants' conduct violated the conditions of the MemoryGel Silicone Breast Implant's PMA and federal regulations and requirements governing the post-marketing conduct, including, but not limited to, 21 CFR §§ 820.90 et seq.; 21 CFR §§ 814 et seq; 21 CFR §§ 820.198 et seq.; §§ 820. 100 et seq.; 21 CFR §§ 820.20 et seq.; 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.184 et seq.; and 21 CFR §§ 820.30.

Defendants' conduct separately violated their duties under California law.

108. Defendants conduct violated these FDA regulations and also separately violated its duties under California state law, thereby jeopardizing the health of patients, including Plaintiff.

109. Defendants failed to timely submit post-approval studies. Defendant's actions violated the conditions of the PMA, and federal regulations and requirements governing the post-marketing conduct of Defendants, including, but not limited to, 21 CFR §§ 814.80 et seq. Defendants' actions also separately violated duties under California law governing their post-market conduct.

110. The FDA also requires that upon purchase of a company holding a PMA, the PMA sponsor "must submit a PMA amendment to notify the FDA of the new owner… The… supplement should include: the effective date of the ownership transfer; a statement of the new owner's commitment to comply with all the conditions of approval applicable to the PMA; and either a statement that the new owner has a complete copy of the PMA including all amendment, supplements, and reports or a request for a copy from the FDA files."

111. Upon information and belief, no PMA supplement notifying the FDA of Mentor's acquisition was submitted. These actions violated the conditions of the PMA and federal regulations and requirements governing the post-marketing conduct of Mentor, including, but not limited to, 21 CFR §§ 814.39 et seq. Defendants' actions also separately violated duties under California law governing their post-market conduct.

112. As presented above, Defendants failed to comply with several of the aforementioned conditions of the PMA and federal regulations, thereby invalidating the PMA.

113. To protect the Mentor MemoryGel Silicone Breast Implant brand, Defendants made a conscious and intentional decision to hide their knowledge of serious safety risks from the FDA and public.

114. The FDA's Office of Regulatory Affairs ("ORA") is the lead office for all field activities, including inspections and enforcement. During an inspection, if ORA investigators observe conditions they deem to be objectionable, these observations are required to be listed on an FDA Form 483 when they indicate that an FDA-regulated product may be in violation of FDA requirements.

115. FDA Form 483s typically are discussed with a company's management team at the conclusion of the inspection. The Form 483 is not an all-inclusive list of every possible deviation from law and regulation. There may be other objectionable conditions that exist that are not cited on the FDA Form 483. Companies must take corrective action to address the cited objectionable conditions and any related, non-cited objectionable conditions that exist.

116. In or around May 1, 2000 to May 10, 2000, the FDA conducted an inspection of Defendant Mentor's facility, noting conditions that it found objectionable and/or constituted violations of the FDCA and related Acts and Regulations. The Form 483 Report was issued May 10, 2000, addressed to the President of Mentor for the Manufacturing Operations Division, and noted that Mentor did not have approved software and system requirements.

117. In or around April 16, 2001 to April 23, 2001, the FDA conducted an inspection of Defendant Mentor's facility, noting conditions that it found objectionable and/or constituted violations of the FDCA and related Acts and Regulations. The Form 483 Report was issued April 23, 2001, addressed to Ramon Ricart, Vice President of Quality and Regulatory Assurance, and noted use of nonconforming products.

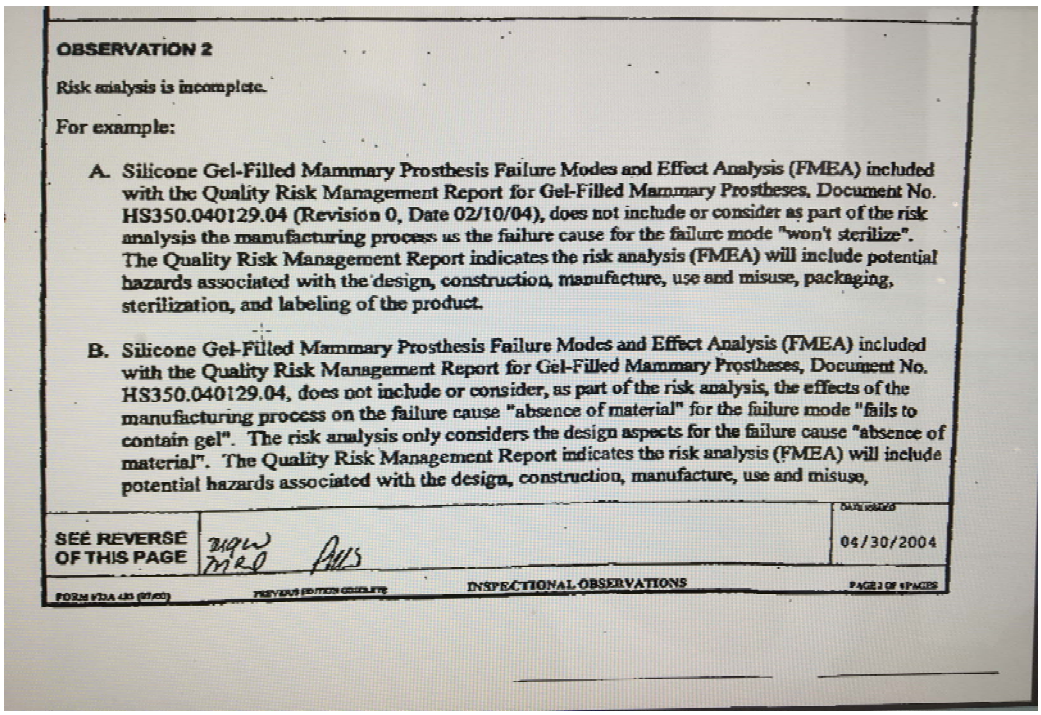
118. In or around February 4, 2002 to February 15, 2002, the FDA conducted an inspection of Defendant Mentor's facility, noting conditions that it found objectionable and/or constituted violations of the FDCA and related Acts and Regulations. The Form 483 Report was issued February 15, 2002, addressed to Ramon Ricart, Vice President of Quality and Regulatory Assurance.

119. In or around April 16, 2003 to April 22, 2003, the FDA conducted an inspection of Defendant Mentor's facility, noting conditions that it found objectionable and/or constituted violations of the FDCA and related Acts and Regulations. The Form 483 Report was issued April 22, 2003, addressed to Al Saalabi, Vice President of Regulatory and Quality Assurance.

120. In or around April 13, 2004 to April 30, 2004, the FDA conducted an inspection of Defendant Mentor's facility, noting conditions that it found objectionable and/or constituted violations of the FDCA and related Acts and Regulations. The Form 483 Report was issued April 30, 2004, addressed to Clarke L. Scherff, Vice President of Regulatory Compliance, citing that:

a. Documents did not include data or statistical rationale to support their sampling plans used to test saline and gel-filled mammary prosthetic finished devices manufactured at Mentor.

b.



OBSERVATION 2

Risk analysis is incomplete.

For example:

A. Silicone Gel-Filled Mammary Prosthesis Failure Modes and Effect Analysis (FMEA) included with the Quality Risk Management Report for Gel-Filled Mammary Prostheses, Document No. HS350.040129.04 (Revision 0, Date 02/10/04), does not include or consider as part of the risk analysis the manufacturing process as the failure cause for the failure mode "won't sterilize". The Quality Risk Management Report indicates the risk analysis (FMEA) will include potential hazards associated with the design, construction, manufacture, use and misuse, packaging, sterilization, and labeling of the product.

B. Silicone Gel-Filled Mammary Prosthesis Failure Modes and Effect Analysis (FMEA) included with the Quality Risk Management Report for Gel-Filled Mammary Prostheses, Document No. HS350.040129.04, does not include or consider, as part of the risk analysis, the effects of the manufacturing process on the failure cause "absence of material" for the failure mode "fails to contain gel". The risk analysis only considers the design aspects for the failure cause "absence of material". The Quality Risk Management Report indicates the risk analysis (FMEA) will include potential hazards associated with the design, construction, manufacture, use and misuse,

SEE REVERSE OF THIS PAGE

04/30/2004

INSPECTIONAL OBSERVATIONS

c. Mentor did not initiate or conduct corrective action to reassess the results and adjust the values of the product bioburden samples taken between

11/23/98 to 2/26/02.

d. Mentor did not adhere to their Environmental Monitoring Program procedure.

121. The FDA Establishment Inspection Report for the 13 day, April 13, 2004 to April 30, 2004 inspection was issued to Mr. Clarke L. Scherff, Mentor's Vice President of Regulatory Compliance, and stated the following, but not limited to:

a. The inspection of the Class III medical device manufacturer was initiated by the Pre-Approval Coordinator, for PMA No. P030053.

b. The purpose of the premarket inspection was to assure compliance with the device current good manufacturing practices (cGMPs), placing emphasis on validation of all significant manufacturing processes conducted on the gel-filled mammary implants.

c. In the FDA Form 483 that was issued, four observations were cited for deficiencies in the sampling methods followed for finished device testing, risk analysis content, investigation of non-conformances, and environmental monitoring control procedures. At the conclusion of the inspection on 4/30/0-4, the Form 483 was issued to Mr. Clare L. Scherff and discussed with the management representatives of the Mentor Corporation.

d. Mentor's responsible individuals included:

i. Clark Scherff, VP Regulatory Compliance

ii. Al Saalabi, VP Quality and Regulatory Assurance

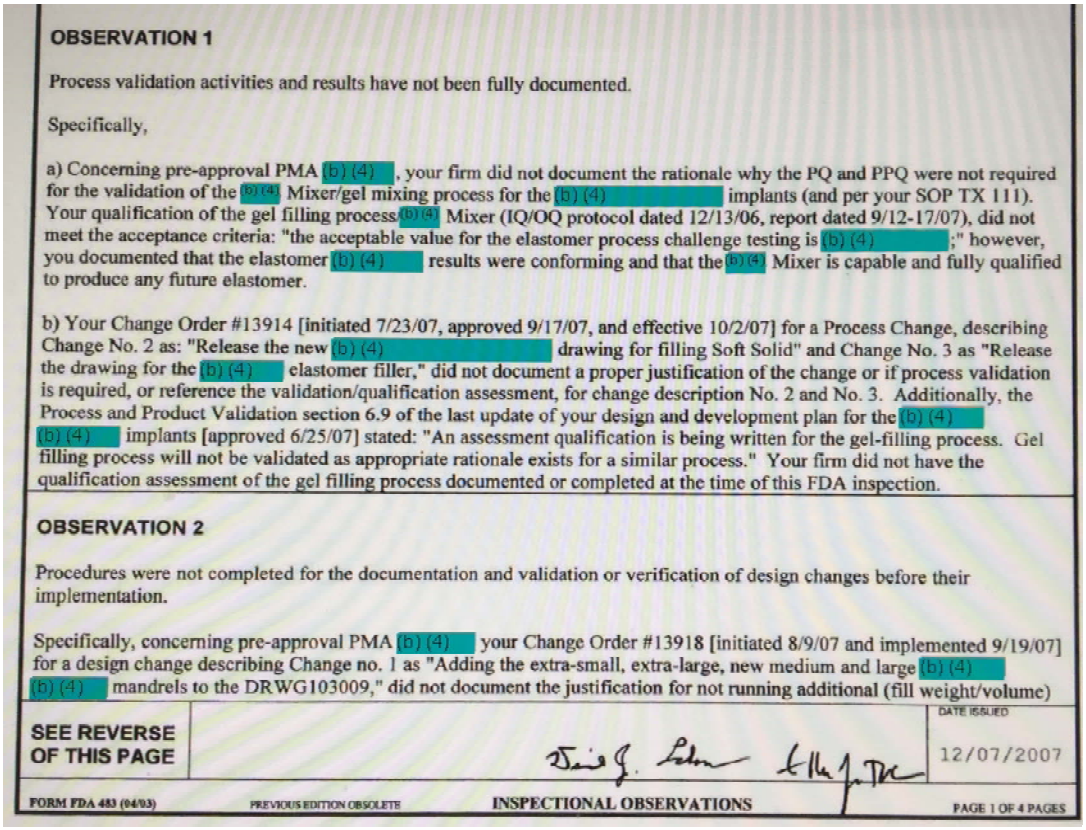
iii. Andrew G. Tymkiw, VP Manufacturing & General Manager Texas Operations

iv. Donald Cox, Director Quality and Regulatory Assurance

v. Udo Graf, Director of Research & Development

vi. Michael Megura, Director Manufacturing Engineering

e. The data provided to justify the performance of finished device testing on



OBSERVATION 1

Process validation activities and results have not been fully documented.

Specifically,

a) Concerning pre-approval PMA (b) (4), your firm did not document the rationale why the PQ and PPQ were not required for the validation of the (b) (4) Mixer/gel mixing process for the (b) (4) implants (and per your SOP TX 111). Your qualification of the gel filling process (b) (4) Mixer (IQ/OQ protocol dated 12/13/06, report dated 9/12-17/07), did not meet the acceptance criteria: "the acceptable value for the elastomer process challenge testing is (b) (4);" however, you documented that the elastomer (b) (4) results were conforming and that the (b) (4) Mixer is capable and fully qualified to produce any future elastomer.

b) Your Change Order #13914 [initiated 7/23/07, approved 9/17/07, and effective 10/2/07] for a Process Change, describing Change No. 2 as: "Release the new (b) (4) drawing for filling Soft Solid" and Change No. 3 as "Release the drawing for the (b) (4) elastomer filler," did not document a proper justification of the change or if process validation is required, or reference the validation/qualification assessment, for change description No. 2 and No. 3. Additionally, the Process and Product Validation section 6.9 of the last update of your design and development plan for the (b) (4) (b) (4) implants [approved 6/25/07] stated: "An assessment qualification is being written for the gel-filling process. Gel filling process will not be validated as appropriate rationale exists for a similar process." Your firm did not have the qualification assessment of the gel filling process documented or completed at the time of this FDA inspection.

OBSERVATION 2

Procedures were not completed for the documentation and validation or verification of design changes before their implementation.

Specifically, concerning pre-approval PMA (b) (4) your Change Order #13918 [initiated 8/9/07 and implemented 9/19/07] for a design change describing Change no. 1 as "Adding the extra-small, extra-large, new medium and large (b) (4) (b) (4) mandrels to the DRWG103009," did not document the justification for not running additional (fill weight/volume)

SEE REVERSE OF THIS PAGE

DATE ISSUED 12/07/2007

FORM FDA 483 (04/03) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 4 PAGES

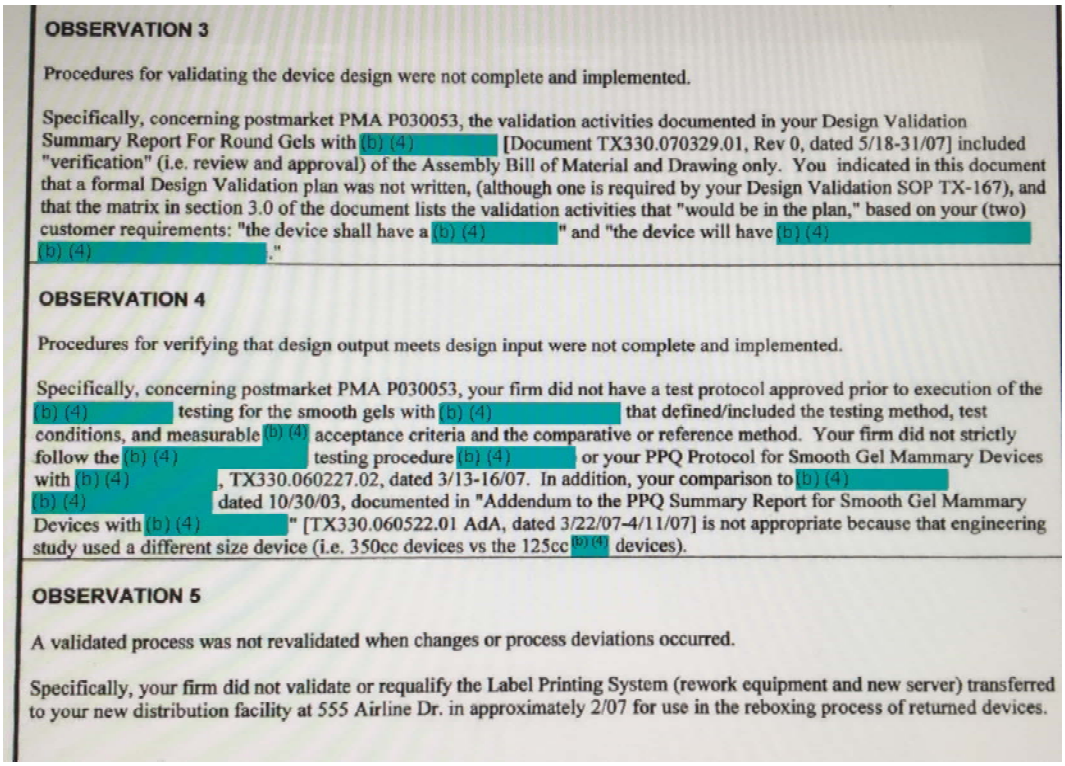
a Skip Lot Sampling Plan for gel-filled products is incomplete and lacks a statistical or technical rationale.

122. In or around November 7, 2007 to December 7, 2007, the FDA conducted an inspection of Defendant Mentor's facility, noting conditions that it found objectionable and/or constituted violations of the FDCA and related Acts and Regulations. The Form 483 Report was issued December 7, 2007, addressed to Steven L. Jackson, Director of Regulatory Compliance and Quality Assurance. This Form 483 noted the following violations:

123. Defendants' actions violated duties under federal law, federal regulations, and California law.

G. Defendants Intentionally and Knowingly Failed to Warn Patients and Physicians

124. Arsenic, antimony, barium, cobalt, mercury, nickel, copper, zinc, chromium, titanium, vanadium, selenium, tin, and molybdenum are chemical



OBSERVATION 3

Procedures for validating the device design were not complete and implemented.

Specifically, concerning postmarket PMA P030053, the validation activities documented in your Design Validation Summary Report For Round Gels with (b) (4) [Document TX330.070329.01, Rev 0, dated 5/18-31/07] included "verification" (i.e. review and approval) of the Assembly Bill of Material and Drawing only. You indicated in this document that a formal Design Validation plan was not written, (although one is required by your Design Validation SOP TX-167), and that the matrix in section 3.0 of the document lists the validation activities that "would be in the plan," based on your (two) customer requirements: "the device shall have a (b) (4) " and "the device will have (b) (4) (b) (4) ."

OBSERVATION 4

Procedures for verifying that design output meets design input were not complete and implemented.

Specifically, concerning postmarket PMA P030053, your firm did not have a test protocol approved prior to execution of the (b) (4) testing for the smooth gels with (b) (4) that defined/included the testing method, test conditions, and measurable (b) (4) acceptance criteria and the comparative or reference method. Your firm did not strictly follow the (b) (4) testing procedure (b) (4) or your PPQ Protocol for Smooth Gel Mammary Devices with (b) (4) , TX330.060227.02, dated 3/13-16/07. In addition, your comparison to (b) (4) (b) (4) dated 10/30/03, documented in "Addendum to the PPQ Summary Report for Smooth Gel Mammary Devices with (b) (4) " [TX330.060522.01 AdA, dated 3/22/07-4/11/07] is not appropriate because that engineering study used a different size device (i.e. 350cc devices vs the 125cc (b) (4) devices).

OBSERVATION 5

A validated process was not revalidated when changes or process deviations occurred.

Specifically, your firm did not validate or requalify the Label Printing System (rework equipment and new server) transferred to your new distribution facility at 555 Airline Dr. in approximately 2/07 for use in the reboxing process of returned devices.

constituents of Mentor's silicone-gel implants and/or are present in the implants as a relic of the manufacturing process. Absent silicone gel bleed beyond that which

Mentor disclosed to the FDA, heavy metals at the levels present in a patient's body, including Plaintiff, would not be found.

125. Mentor's Product Insert Data Sheet regarding the implants state that "[s]mall quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse ("bleed") through an intact implant shell.....Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact MemoryGel Breast Implants into the body....Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence." ***See Exhibit I,*** Product Insert Data Sheet, pg. 19.

126. The nature and extent of Plaintiff's injuries evidence a significant gel bleed, as opposed a bleed of "small quantities" of gel, or "extremely low level of gel bleed."

127. Mentor failed to warn consumers, healthcare providers, and the FDA that a significant gel bleed was a potential risk of a properly manufactured MemoryGel Silicone Gel Breast Implant.

128. The risk of a significant gel bleed was not disclosed or discussed in what Mentor calls its "Directions for Use" or in its consumer labeling, despite the availability of substantial evidence that such was a significant potential risk of use, even in a properly manufactured product, was present.

129. Gel-filled implants, including MemoryGel, enable gel bleed even through an intact shell which results in microdispersion. Implant ruptures cause macrodispersions, which can make the patient, including Plaintiff, gravely ill.

130. In a June 2011 FDA report on breast implants entitled "FDA Update on the Safety of Silicone Gel-Filled Breast Implants," (***See Exhibit J,*** FDA Update), the FDA pointed out, among other things, that:

a. Patient follow-up rates were lower than anticipated, which limited the ability to draw definitive conclusions and to detect complications.

b. The primary goals of the FDA's post-market medical device surveillance are to identify previously unrecognized adverse events and to help detect patterns of actual or potential adverse events.

c. Mentor must submit adverse event reports on silicone gel-filled breast implants received after November 2006 through one of two reporting methods:

i. Medical Device Reports (MDR)- manufacturers must report all deaths and unusual, unique, or uncommon adverse events to the FDA as individual reports on the FDA Form 3500A within 30 days of becoming aware of the event, or

ii. Postmarket Spreadsheet Reports (PSR)- manufacturers must report serious injuries and malfunctions that are well-known or expected to occur based on data from the premarket clinical trials in PSR reports. PSR reports are submitted quarterly, as authorized under 21 CFR Part 803.19(c), as an alternative to the requirement for submitting individual MDR reports on FDA Form 3500A.

1. The FDA designed the PSR program specifically to monitor the postmarket performance of approved silicone gel-filled breast implants. The PSR program, an alternative to the requirement for submitting individual MDR reports, requires manufacturers to submit quarterly reports for serious injuries and malfunctions that are well-known or expected to occur based on data from the premarket clinical trials (e.g., rupture, capsular contracture).

d. Because the number of patient and device problems reported to the FDA is subject to underreporting, MAUDE and PSR data are not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.

131. The FDA advised that, since Mentor began post-approval studies in 2007, Mentor found 43.5% of implants retrieved from patients participating in the large post-approval study had ruptures, and 25% of 97 implants that were explanted and returned to Mentor for evaluation from August 2000 to August 2009 in the Core Study had ruptured.

132. Based upon Mentor's reports, the FDA separately stated that "The most common cause of rupture reported in the device retrieval studies is damage to the implant during the implantation surgery. However, only a small proportion of breast implants are returned to the manufacturers for evaluation. This limits the ability to identify trends in failure modes." It is unclear what "damage to the implant during surgery" means, whether due to the foreseeable handling of the devices, weakness in the shell due to manufacturing defects, or other foreseeable factors.

133. Mentor knew of multiple risks associated with implants, and responded by terminating post-market studies, failing to conduct required follow-up, sponsoring only self-serving research they could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies. Mentor's duty to the scientific community and women who have undergone augmentation for any reason-at the insistence of the FDA-was to design an effective study.

134. Mentor intentionally and systematically failed to make this happen which is a violation of the FDA's directives for compliance with the conditions of approval of the PMA.

V. PLAINTIFF REXINA MIZE'S INJURIES

135. Plaintiff Rexina Mize underwent a bilateral breast augmentation procedure on September 27, 2000, wherein Mentor MemoryGel® Silicone breast implants (the "product") were implanted in Los Angeles, California. ***See Exhibit K,*** Product Identification Labels.

136. Upon information and belief, Plaintiff may have been part of Mentor's Core Study, but was not contacted for follow-up.

137. Prior to her breast augmentation, Plaintiff enjoyed an active, full life, and did not experience any of the symptoms she would soon experience after her implants. Plaintiff was a musician and a singer in a band, and performed often.

138. Subsequently after her implant surgery with the product, she began experiencing extreme and chronic fatigue, muscle pain, muscle weakness, muscle cramps, bone pain, swelling in her joints, pain in her joints, stiffness in her joints, severe memory loss, mental confusion, irritability, shortness of breath, severe migraines, itching, nausea, dizziness, numbness in her extremities, vision dysfunction, skin rashes, signs of silicone toxicity, autoimmune issues, weight gain, hormonal problems, heart palpitations, and extreme sensitivity to coldness. Plaintiff's vision was so compromised that she had to get glasses in order to see. Plaintiff's chronic fatigue was so pervasive and continuous that there were many days she could not even get out of bed in the morning. Plaintiff had to give up her music and singing in the band as a result of the chronic fatigue and other symptoms which prevented her from performing. Plaintiff also missed several business opportunities due to the presence of her chronic symptoms. Plaintiff maintains a health and nutritious diet at all times relevant. Plaintiff reported these symptoms to her physician throughout the years since her implant surgery. Her physicians did not connect it to her Mentor MemoryGel® silicone breast implants.

139. In or around the latter part of 2016, Plaintiff reported to her physician that her left implant was causing her severe pain. Her physician ordered an MRI. On or about December 6, 2016, Plaintiff had an MRI to assess her bilateral breast implants, which revealed bilateral subpectoral silicone implants demonstrating rupture of the right implant.

140. On or about a blood test from December 29, 2016, Plaintiff's sed rate was elevated above the normal reference range.

141. On or about January 3, 2017, Plaintiff underwent explant surgery to remove the bilateral silicone breast implants. The procedure entailed a bilateral total capsulectomy and implant removal. Her postoperative diagnosis revealed there was a right extracapsular and left intracapsular rupture of the silicone breast implants. As noted in the operative report, "both implant capsular complexes were examined.

There was obvious silicone present on the outer capsule of the right side. Both capsules were incised. There was obvious free silicone gel on the right side and surprisingly some stranding of the silicone gel on the left side as well. Closer examination of the left implant showed smooth, round, 400 cc of silicone implant with a small hole. The right side showed smooth, round, 400 cc silicone gel implant with large tear."

142. On or about January 5, 2017, the surgical pathology report from the bilateral implant removal surgery performed on January 3, 2017 reported the following diagnosis:

a. Left breast, capsulectomy – hyalinized fibrous tissue with calcifications, foamy macrophages, and focal chronic inflammation.

b. Right breast, capsulectomy – hyalinized fibrous tissue with histiocytic reaction to foreign material, calcifications, and focal chronic inflammation.

143. After her surgery, the majority of Plaintiff's symptoms and injuries caused by the Mentor silicone implants have improved, but Plaintiff is still working to get her health back. Plaintiff no longer requires glasses in order to see, and her chronic fatigue has been decreased, even during the healing process after the explant surgery. Plaintiff's mental clarity has improved.

VI. CAUSES OF ACTION

FIRST CAUSE OF ACTION
NEGLIGENCE & NEGLIGENCE PER SE
(Against All Defendants)

144. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

145. At all relevant times, Defendants had a duty to Plaintiff to use reasonable

care in formulating, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting Mentor MemoryGel Silicone Gel Breast Implants.

146. Defendants formulated, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Mentor MemoryGel Silicone Gel Breast Implants, including the product that was implanted into Plaintiff Rexina Mize.

147. Defendants had a duty under parallel state law, including California law, to exercise reasonable care to provide adequate warning about the risks and dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Defendants at the time of distribution.

148. Defendants breached their duty in that they failed to warn Plaintiffs and their physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Mentor MemoryGel Silicone Gel Breast Implants prior to the time of Plaintiff's implantation, including the actual level of risk and failure to communicate adverse events similar to the injuries suffered by Plaintiff.

149. Specifically, upon information and belief, Defendants breached these duties and violated federal and state law by, inter alia: receiving and failing to warn of or report adverse events to the FDA or the public; failing to warn of or report Mentor MemoryGel Silicone Gel Breast Implants failure to meet its performance specifications or perform as intended under the PMA and FDA requirements; and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Mentor MemoryGel Silicone Gel Breast Implants, including but not limited to:

a. instances of ruptured;

b. instances of silicone toxicity;

c. instances of adverse events;

d. instances of adverse events requiring removal;

e. instances of constellations of adverse symptoms;

f. instances of chronic/persistent autoimmune-like complaints and inflammatory issues;

150. Despite the fact that evidence existed that Mentor MemoryGel Silicone Gel Breast Implants were dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Mentor MemoryGel Silicone Gel Breast Implants. Instead, Defendants manufactured, marketed, sold, advertised, and promoted Mentor MemoryGel Silicone Gel Breast Implants while failing to warn or otherwise ensure the safety of its users in violation of state law, including California law, the Mentor MemoryGel Silicone Gel Breast Implants PMA, and FDA regulations.

151. In addition, the Mentor MemoryGel Silicone Gel Breast Implant's PMA set forth six specific studies and reporting requirements - as described above - that obligated Defendants to report their results.

152. Defendants negligently failed to comply with the above requirements and failed to take necessary actions - such as filing PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs - to advise users of Mentor MemoryGel Silicone Gel Breast Implants of the defects and risks described above.

153. Defendants had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded. Health & Saf. Code, §§ 111440 ("it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded"), 111445 ("it is unlawful for any person to misbrand any drug or device.").

154. Under parallel federal law, Defendants had the ability to disclose its knowledge of adverse events to healthcare providers and the public to ensure its

labeling and product were not misbranded. 21 U.S.C. § 331 ("the following acts and the causing thereof are prohibited: (a) the introduction…of any device that is …misbranded, (b) the …misbranding of any …device…).

155. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiff's physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiff's physician, regarding the dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Defendants at the time of distribution.

156. If Plaintiff and Plaintiff's physician been adequately warned of the serious risks and adverse events, they would not have agreed to or used Mentor MemoryGel Silicone Gel Breast Implants. As a proximate and legal result of Defendants' failure to comply with its PMA and FDA post-marketing regulations, Defendants breached their duty of care to Plaintiff under parallel state law and caused Plaintiff past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

157. Defendants owed a duty in all of their several undertakings, including the communication of information concerning Mentor MemoryGel Silicone Gel Breast Implants, and to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

158. Defendants, in the course of their business and profession, knowingly and negligently disseminated inaccurate and misleading information to physicians concerning the properties and effects of Mentor MemoryGel Silicone Gel Breast Implants, with the intent and expectation that physicians would rely on that information in their decisions in recommending and surgically implanting Mentor MemoryGel Silicone Gel Breast Implants in their patients.

159. When Defendants disseminated information to physicians and/or patients concerning the properties and effects of Mentor MemoryGel Silicone Gel Breast Implants, they knew or should have known that physicians and/or patients would reasonably rely on that information in their decisions concerning the use of Mentor MemoryGel Silicone Gel Breast Implants.

160. Defendants disseminated false information, in that they engaged in false and misleading sales and marketing tactics, touting the aesthetic beauty of breast augmentation and minimizing the risks, which reached physicians, the medical community, and the public with knowledge that the information was, in fact, false and misleading.

161. Defendants produced false and misleading sales and marketing tactics and concealed adverse information at a time when Defendants knew, or should have known, that Mentor MemoryGel Silicone Gel Breast Implants had defects, dangers, and characteristics that were other than what Defendants had represented to consumers and the healthcare industry generally.

162. Defendants had no reasonable grounds for believing these representations were true when they were made; in fact, Defendants knew the representations to be false.

163. Defendants' breach of their duties under state law parallel to their violations of federal law; the Mentor MemoryGel Silicone Gel Breast Implants PMA specifically mandates, and state law independently requires, that any representations regarding the device must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

164. Defendants disseminated the false information, as referenced above, to physicians, the medical community, and the public with the intention to deceive physicians and their patients and to induce physicians to surgically implant Mentor MemoryGel Silicone Gel Breast Implants.

165. In willfully supplying the false and misleading information, Defendants

negligently failed to exercise reasonable care to ensure that the information disseminated to physicians and patients concerning the properties and effects of Mentor MemoryGel Silicone Gel Breast Implants was accurate and not misleading.

166. By failing to ensure representations regarding Mentor MemoryGel Silicone Gel Breast Implants were truthful, accurate, and not misleading, Defendants have violated the Mentor MemoryGel Silicone Gel Breast Implants PMA, FDA regulations, and parallel state law.

167. Defendants expected or should have expected that patients, in reliance on false information, who were implanted with Mentor MemoryGel Silicone Gel Breast Implants would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to Mentor MemoryGel Silicone Gel Breast Implants, causing them to undergo future removal surgeries.

168. Plaintiff and/or Plaintiff's physicians did in fact reasonably rely on Defendants' negligent misrepresentations, as Defendants intended.

169. As a proximate and foreseeable result of the foregoing misrepresentations by Defendants, Plaintiff has suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

170. Under federal law and regulations, Defendants were under a continuing duty to comply with the requirements listed in their PMA and with the FDCA in the manufacture, development, promotion, marketing, labeling, distribution, testing, and sale of Mentor MemoryGel Silicone Gel Breast Implants. 21 U.S.C. §§ 301, et seq; 21 U.S.C. § 360l (postmarket surveillance).

171. Violations of the following federal regulations also constitute violations of Defendants' parallel state law duties and give rise to negligence per se: 21 C.F.R. § 803.10; 21 C.F.R. § 803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21, C.F.R. § 806; 21 C.F.R. § 814.1; 21 C.F.R. § 814.3; 21 C.F.R. § 814.9; 21

C.F.R. § 814.20; 21 C.F.R. § 814.37; 21 C.F.R. § 814.39; 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. § 820.1; 21 C.F.R. § 820.5; 21 C.F.R. § 820.20; 21 C.F.R. § 820.22; 21 C.F.R. § 820.25; 21 C.F.R. § 820.30; 21 § C.F.R. 820.70; 21 § 820.90; and 21 C.F.R. § 820.160.

172. Defendants' conduct also violates their duties under the Sherman Food, Drug, and Cosmetic laws and gives rise to negligence per se. West's Ann. Cal. Health & Safety Code §§ 109875, et. seq.; 111260; 111295; 111300; 111305; 111440; 111445; and 111450.

173. Plaintiff is within the class of persons the statutes and regulations protect, and Plaintiff's injuries are of the type of harm these statutes and regulations are designed to prevent.

174. Defendants' violations of these statutes and regulations proximately caused Plaintiff's injuries alleged herein.

175. The conditions of the Mentor MemoryGel Silicone Gel Breast Implants PMA incorporate these statutes and regulations. Failure to comply with the conditions of approval invalidates the PMA. See 21 C.F.R. § 814.82(c).

176. Defendants had a parallel duty under state law, including California law, to exercise reasonable care in testing and inspecting their product, in monitoring conformity with the design of Mentor MemoryGel Silicone Gel Breast Implants placed into Plaintiff, in performing continuing risk-analysis and risk assessments of Mentor MemoryGel Silicone Gel Breast Implants, in manufacturing Mentor MemoryGel Silicone Gel Breast Implants, and in marketing Mentor MemoryGel Silicone Gel Breast Implants to the public.

177. Defendants were negligent under state law, including California law, in their development, promotion, marketing, manufacture, distribution, and/or sale of Mentor MemoryGel Silicone Gel Breast Implants in one or more of the following particulars:

a. manufacturing actual Mentor MemoryGel Silicone Gel Breast Implants

that differ from the specifications set forth in the PMA, its Supplements, the Conditions of Approval, and/or other federal regulations;

b. manufacturing actual Mentor MemoryGel Silicone Gel Breast Implants with nonconforming materials and uncertified components, inconsistent with the specifications set forth in the PMA, its Supplements, the Conditions of Approval and/or other federal regulations;

c. failing to conduct regular risk analysis of Mentor MemoryGel Silicone Gel Breast Implant;

d. failing to properly meet the applicable standard of care by not complying with applicable federal regulations;

e. carelessly and negligently selling and distributing Mentor MemoryGel Silicone Gel Breast Implants in violation of the PMA and federal law;

f. negligently incorporating components into Mentor MemoryGel Silicone Gel Breast Implants that could not stand up to normal usage;

g. failing to exercise reasonable care in its inspecting and testing of the product; and

h. failing to exercise reasonable care in its manufacturing and quality control processes.

178. Despite the fact that Defendants knew or should have known that Mentor MemoryGel Silicone Gel Breast Implants caused unreasonable, dangerous side effects, Defendants continued to promote and market Mentor MemoryGel Silicone Gel Breast Implants to consumers, including Plaintiff, and their healthcare providers.

179. Defendants also had a duty under state law, including California law, to exercise ordinary care in the manufacture of Mentor MemoryGel Silicone Gel Breast Implants consistent with FDA specifications, the Mentor MemoryGel Silicone Gel Breast Implants PMA, and/or conditions of approval.

180. At all relevant times, Defendants were required to comply with the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. §

820.1, et seq., which, among other things, require that each manufacturer put procedures in place to test products for compliance with product specifications, document and check compliance with product specifications before products are accepted for sale and use, and identify and control all products that fail to conform with product specifications.

181. The Mentor MemoryGel Silicone Gel Breast Implants contained a manufacturing defect when it left Defendants' possession, in that Defendants' manufacturing process did not conform to the FDA's current good manufacturing practices ("cGMP") design controls enumerated in 21 C.F.R. § 820.30.

182. Upon information and belief, Defendant Mentor has received several Form 483 violations and establishment inspection reports ("EIR") which exemplified its failing to comply with statutes and regulations.

183. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Mentor MemoryGel Silicone Gel Breast Implants. For instance, on August 3, 2016, a Class 2 recall was issued for the Mentor MemoryGel Breast Implants, recall number Z-2326-2016. ***See Exhibit L***, Recall Notice. This recall was based on labeling mix-ups, including that the box of 300cc MemoryGel Breast Implants were labeled with null manufacturing and expiration dates. Products subject to this recall were distributed in New York, Wisconsin, California, Texas, Colorado, North Carolina, New Jersey, Ohio, Tennessee, Rhode Island, and Illinois.

184. Defendants failed to adequately inspect, test, and validate the materials and components used in the manufacture and assembly of Mentor MemoryGel Silicone Gel Breast Implants.

185. Defendants failed to adequately inspect, test, and validate Mentor MemoryGel Silicone Gel Breast Implants after completion of assembly and immediately before delivery for implantation into Plaintiff.

186. Defendants failed to comply with the regulations and testing requirements

imposed by the granting of the PMA by the FDA for the Mentor MemoryGel Silicone Gel Breast Implants, including the requirement that follow-through studies by conducted. Upon information and belief, Plaintiff may have been a participant in the Core Study, and was not contacted for follow-up.

187. Because Defendants failed to follow specifications, regulations, and required Good Manufacturing Practices, Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were vulnerable to degradation, deterioration, ruptures, and leakage.

188. Upon information and belief, when Mentor MemoryGel Silicone Gel Breast Implants was manufactured, Defendants had the technological capability to manufacture Mentor MemoryGel Silicone Gel Breast Implants in a reasonably safe manner and is held to the level of knowledge of an expert in the field. Defendant Mentor touts itself as a global leader in aesthetic medicine. For over 20 years, more than 5 million women have used Mentor breast implants, making Mentor one of the global leaders in breast aesthetics.

189. Upon information and belief, Plaintiff was implanted with Mentor MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the PMA specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff. The injuries Plaintiff suffered are expected to result from the manufacturing defects identified therein. Plaintiff and her physician were unaware that the device was defective at the time of implant and for years thereafter.

190. As a proximate and legal result of Defendants' failure to exercise reasonable care and the resulting defective condition of Mentor MemoryGel Silicone Gel Breast Implants implanted into Plaintiff caused Plaintiff's injuries described infra, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future follow-up medical care, medical treatment, and procedures, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

191. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against All Defendants)

192. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

193. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Mentor MemoryGel Silicone Gel Breast Implants.

194. At all times relevant herein, Defendants intended for the MemoryGel Silicone Gel Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiff, and knew or should have known that the product would be surgically implanted into members of the general public, including Plaintiff.

195. Defendants failed to warn Plaintiff and her physicians of the risk of serious defects and life altering complications described herein rendering the device defective and unreasonably dangerous.

196. Defendants also failed to revise their labeling to warn of the accurate rate of occurrence of adverse events based upon the post-market adverse event information available to them.

197. Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants was defective at the time of sale and distribution and at the time they left the possession of Defendants in that Defendants failed to adequately warn of the risks that the product was vulnerable to degradation, deterioration, ruptures, and leakage, and other injuries associated with Mentor MemoryGel Silicone Gel Breast Implants. The MemoryGel

Silicone Gel Breast Implants were defective and unreasonably dangerous when they left the possession of Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and complications associated with the MemoryGel Silicone Gel Breast Implants, including but not limited to, their propensity to cause injury, through leakage of the silicone gel into the tissues of the user's body, thereby introducing toxic metals and chemicals into those tissues, resulting in serious, dangerous and harmful side effects and complications all to the detriment of the health and well-being of the users of their product, including Plaintiff.

198. Defendants knew or should have known the gel contained in the implants contained metals and toxic chemicals in such quantities that would be extremely harmful to users of their product if the gel were allowed to escape its shell and "bleed" into the user's body. Defendants also knew or should have known that there was a significant risk of rupture or seepage of the gel through the shell and into the tissues of the user's body. Defendants failed to adequately warn users, including Plaintiff, of Defendants' products and of these potential serious and harmful risks.

199. Defendants failed to provide follow-through post-approval studies required by the FDA's granting of the PMA necessary in order to market and sell their product, and thus failed to report to, and warn, the FDA of the risks described above.

200. The accurate rate of occurrence for these and other injuries associated with Mentor MemoryGel Silicone Gel Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's physician, as a result of Defendants' conduct.

201. Mentor MemoryGel Silicone Gel Breast Implants were defective and unreasonably dangerous due to inadequate warnings and/or instruction because Defendants knew or should have known that the products created a serious risk of degradation, deterioration, ruptures, and leakage, and other injuries that could, and did, harm consumers, including Plaintiff, and Defendants failed to adequately warn

consumers of said risks - including Plaintiff and/or her physician- in accordance with state law, including California law.

202. Mentor MemoryGel Silicone Gel Breast Implants manufactured and sold by Defendants were defective and unreasonably dangerous due to inadequate warnings and instructions because Defendants knew or should have known that Mentor MemoryGel Silicone Gel Breast Implants created, among other things, a higher than expected risk for adverse events, and Defendants failed to adequately warn of those risks, to monitor those risks, report them, test for them, and update its labeling regarding such risks when the information became available.

203. At all relevant times, Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were used and implanted into Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

204. Mentor MemoryGel Silicone Gel Breast Implants manufactured, marketed, promoted, distributed, and sold by Defendants were expected to, and did, reach Plaintiff and/or Plaintiff's physician without substantial change in the condition in which they were sold.

205. Despite the fact that Defendants knew or should have known that the use of Mentor MemoryGel Silicone Gel Breast Implants were unreasonably dangerous and likely to place users at serious risks to their health, Defendants failed to monitor and warn of the defects, health hazards, and risks associated with Mentor MemoryGel Silicone Gel Breast Implants.

206. Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were also defective at the time of sale and distribution, and at the time the devices left the possession of Defendants, in that the devices differed from Defendants' intended result and design specifications.

207. Upon information and belief, Plaintiff was implanted with Mentor MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the PMA

specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff, requiring surgery. The injuries Plaintiff suffered are expected to result from the manufacturing defects identified therein and by the FDA. Plaintiff and her physician were unaware that the device was defective at the time of implant and for years thereafter.

208. Defendants violated state law, including California law, by placing the Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce in a defective and unreasonably dangerous condition.

209. Mentor MemoryGel Silicone Gel Breast Implants had a manufacturing defect when they left Defendants' possession in that Defendants' manufacturing process did not conform to the cGMP design controls enumerated in 21 C.F.R. § 820.30.

210. The defects inherent in Mentor MemoryGel Silicone Gel Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's physician.

211. Plaintiff could not, in the exercise of reasonable care, have discovered the defects herein mentioned and perceived their true danger.

212. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendants, including Defendant Mentor, when she consented to the implantation procedure using Mentor MemoryGel Silicone Gel Breast Implants.

213. At all relevant times, Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

214. Had Plaintiff and/or Plaintiff's physician received adequate warnings regarding the risks the risks of Mentor MemoryGel Silicone Gel Breast Implants, she would not have used them.

215. Mentor MemoryGel Silicone Gel Breast Implants manufactured, designed,

promoted, marketed, distributed, and sold by Defendants were expected to, and did, reach Plaintiff and/or Plaintiff's physician without substantial change in the condition in which they were sold.

216. Defendants knew that Mentor MemoryGel Silicone Gel Breast Implants would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

217. At all times relevant to this action, the dangerous propensities of Mentor MemoryGel Silicone Gel Breast Implants were known to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to implant Mentor MemoryGel Silicone Gel Breast Implants for their patients.

218. Defendants were required to provide adequate warnings to consumers and the medical community under federal and state law, including California law, but failed to do so in a timely and responsible manner.

219. Had Defendants timely and adequately reported adverse events to the FDA, there would have been effective warnings to physicians, including Plaintiff's physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiff and/or Plaintiff's physician, regarding the dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Defendants at the time of distribution.

220. Because Defendants failed to follow specifications, regulations, and required Good Manufacturing Practices, Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were vulnerable to degradation, deterioration, ruptures, and leakage.

221. Mentor MemoryGel Silicone Gel Breast Implants, which was manufactured, distributed, tested, sold, marketed, promoted, advertised, and

represented defectively by Defendants, was a substantial contributing factor in bringing about Plaintiff's injuries, which would not have occurred but for the use of Mentor MemoryGel Silicone Gel Breast Implants.

222. The defective warnings were a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of Mentor MemoryGel Silicone Gel Breast Implants.

223. The defective manufacturing was a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of Mentor MemoryGel Silicone Gel Breast Implants.

224. As a proximate result and/or substantial factor of Mentor MemoryGel Silicone Gel Breast Implants defective condition at the time they were sold, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

225. By reason of the foregoing, Plaintiff has been damaged by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

226. The wrongful acts, representations and/or omissions of Defendants, hereinabove set forth, were made, adopted, approved, authorized, endorsed and/or ratified by Defendants' officers, directors, or managing agents, and were done maliciously, oppressively, fraudulently and/or with a willful and knowing disregard of the probably dangerous consequences for the health and safety of its products users, including Plaintiff. In making, adopting, approving, authorizing, endorsing and/or ratifying such conduct hereinabove set forth, the officers, directors and/or managing agents of Defendants acted with a willful and/or knowing disregard of the probably dangerous consequences, and/or acted with an awareness of the

probably dangerous consequences of their conduct and deliberately dialed to avoid those consequences, thereby creating a substantial risk of injury to Plaintiff and other users of their products. Plaintiffs are entitled to punitive and exemplary damages in an amount to be ascertained, which is appropriate to punish to set an example of Defendants and deter such behavior by them in the future.

227. WHEREFORE, Plaintiffs prays for judgment against Defendants as set forth.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against All Defendants)

228. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

229. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Mentor MemoryGel Silicone Gel Breast Implants.

230. At all times relevant herein, Defendants intended for the MemoryGel Silicone Gel Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiff, and knew or should have known that the product would be surgically implanted into members of the general public, including Plaintiff.

231. Defendants manufactured, tested, marketed, promoted, advertised, distributed, and sold the Mentor MemoryGel Silicone Gel Breast Implants that were implanted into Plaintiff.

232. At all times relevant, Defendant placed Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce, and did so in a manner in which the Mentor MemoryGel Silicone Gel Breast Implants were defective in their manufacturing due to not meeting the current good manufacturing practices required

by the FDA under the terms and conditions of the PMA.

233. Defendants violated state law, including California law, by placing the Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce in a defective and unreasonably dangerous condition.

234. Defendants' Mentor MemoryGel Silicone Gel Breast Implants implanted during Plaintiff's surgery contained a manufacturing defect. The rupture, leakage, and bleeding of silicone of the Mentor MemoryGel Silicone Gel Breast Implants implanted into Plaintiff, due to porous or weak containment in the Implant shell, is inconsistent with specifications and conditions of the product submitted in the PMA to the FDA for approval, and therefore constitutes a manufacturing defect.

235. Defendants' actions, hereinafter described, violate the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, et seq., which, among other things, require that each manufacturer put procedures in place to test products for compliance with product specifications, document and check compliance with product specifications before products are accepted for sale and use, and identify and control all products that fail to conform with product specifications.

236. Defendants knew that the defect was such that it would not be discovered through

reasonable inspection by the users of the product, including Plaintiff. Defendants knew that Mentor MemoryGel Silicone Gel Breast Implants would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

237. Plaintiff and Plaintiff's physician, foreseeable users and ultimate consumers of the Defendants' product, were unaware of these defects when Plaintiff consented to have them implanted in her body.

238. As a direct and legal result of the manufacturing defects contained in their MemoryGel Silicone Gel Breast Implants, Plaintiff was injured in her health and well-

being as described hereinabove when the toxins contained in the gel began to seep into the tissues of her body, causing a constellations of symptoms and injuries.

239. As a proximate result and/or substantial factor of Mentor MemoryGel Silicone Gel Breast Implants defective condition at the time they were sold, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

240. By reason of the foregoing, Plaintiff has been damaged by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

241. The wrongful acts, representations and/or omissions of Defendants, hereinabove set forth, were made, adopted, approved, authorized, endorsed and/or ratified by Defendants' officers, directors, or managing agents, and were done maliciously, oppressively, fraudulently and/or with a willful and knowing disregard of the probably dangerous consequences for the health and safety of its products users, including Plaintiff. In making, adopting, approving, authorizing, endorsing and/or ratifying such conduct hereinabove set forth, the officers, directors and/or managing agents of Defendants acted with a willful and/or knowing disregard of the probably dangerous consequences, and/or acted with an awareness of the probably dangerous consequences of their conduct and deliberately dialed to avoid those consequences, thereby creating a substantial risk of injury to Plaintiff and other users of their products. Plaintiffs are entitled to punitive and exemplary damages in an amount to be ascertained, which is appropriate to punish to set an example of Defendants and deter such behavior by them in the future.

242. WHEREFORE, Plaintiffs prays for judgment against Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against All Defendants)

243. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

244. At all relevant times, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, marketed, advertised, and sold Mentor MemoryGel Silicone Gel Breast Implants.

245. Prior to Plaintiff's implantation of Mentor MemoryGel Silicone Gel Breast Implants, Defendants impliedly warranted to Plaintiff and Plaintiff's health care providers that Mentor MemoryGel Silicone Gel Breast Implants was of merchantable quality, reasonably fit for its intended purpose, and safe for the use for which it was intended.

246. Defendants also warranted that Mentor MemoryGel Silicone Gel Breast Implants was safer and more effective than other prior generations of breast implants.

247. At all relevant times, Plaintiff and Plaintiff's physician used and implanted Mentor MemoryGel Silicone Gel Breast Implants for the purpose and in the manner intended by Defendants.

248. At all relevant times, Mentor MemoryGel Silicone Gel Breast Implants was not reasonably safe for its expected purpose, nor reasonably fit for the ordinary purpose for which it was sold and/or used and it did not meet the expectations for the performance of the product when used in a customary, usual and reasonably foreseeable manner.

249. Plaintiff and/or her healthcare provider reasonably relied upon the skill and judgment of Defendants and upon said warranties in using Mentor MemoryGel Silicone Gel Breast Implants.

250. Defendants' breaches of their implied warranties under state law parallel

their violations of federal law; the Mentor MemoryGel Silicone Gel Breast Implants PMA specifically mandates, and state law, including California law, independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

251. As soon as the true nature of Mentor MemoryGel Silicone Gel Breast Implants and the fact that the warranties and representations were false was ascertained, Defendants were on notice of the breach of said warranties.

252. As a direct and legal result of the manufacturing defects contained in their MemoryGel Silicone Gel Breast Implants, Plaintiff was injured in her health and well-being as described hereinabove when the toxins contained in the gel began to seep into the tissues of her body, causing a constellations of symptoms and injuries.

253. As a proximate result and/or substantial factor of Mentor MemoryGel Silicone Gel Breast Implants defective condition at the time they were sold, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

254. By reason of the foregoing, Plaintiff has been damaged by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

255. WHEREFORE, Plaintiffs prays for judgment against Defendants as set forth.

FIFTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(Spouse Plaintiff Minh Nguyen as Against All Defendants)

256. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows:

257. At all relevant times hereto, Spouse Plaintiff MINH NGUYEN was and is the lawful spouse of Plaintiff REXINA MIZE.

258. As a result of the injuries and damages suffered by Plaintiff REXINA MIZE by Defendants' defective Mentor MemoryGel Silicone Gel Breast Implants, she was unable to perform any activities as a spouse in the household. Plaintiff REXINA MIZE was unable to take care of the house or provide companionship to Spouse Plaintiff MINH NGUYEN. Spouse Plaintiff MINH NGUYEN had to take full control over chores and acts around the house, including but not limited to, laundry, dishes, cooking, errands, cleaning taking Plaintiff REXINA MIZE to medical treatment, and taking care of Plaintiff REXINA MIZE's needs. Spouse Plaintiff MINH NGUYEN effectively lost the companionship and accompaniment of his wife, Plaintiff REXINA MIZE, as a result of Defendant's defective Mentor MemoryGel Silicone Gel Breast Implants.

259. As a direct and proximate result of the injuries sustained by Plaintiff REXINA MIZE and caused by Defendants, Spouse Plaintiff MINH NGUYEN suffered, and will continue to suffer the loss of his wife's consortium, companionship, society, affection, services and support.

260. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

REQUEST FOR PUNITIVE DAMAGES

261. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

262. At all times relevant herein, Defendants:

a. failed to properly conduct post-approval studies;

b. knew or should have known that Mentor MemoryGel Silicone Gel Breast Implants were dangerous and ineffective;

c. concealed the dangers and health risks from Plaintiff, physicians, other medical providers, the FDA, and the public at large;

d. attempted to misrepresent and did knowingly make misrepresentations to Plaintiff, physicians, and other medical providers, and the public in general as to the safety and efficacy of Mentor MemoryGel Silicone Gel Breast Implants; and

e. with full knowledge of the health risks associated with Mentor MemoryGel Silicone Gel Breast Implants and without adequate warnings of the same, manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mentor MemoryGel Silicone Gel Breast Implants for use.

263. Defendants, by and through its officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiffs and the public, acted with willful, wanton, conscious, and/or reckless disregard for the safety of Plaintiffs and the general public.

264. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety of Mentor MemoryGel Silicone Gel Breast Implants. Defendants' conduct was willful, wanton, and undertaken with a disregard for Plaintiff's rights.

265. Defendants' intentional and/or reckless conduct deprived Plaintiff of necessary information to enable her to weigh the true risks of using Mentor MemoryGel Silicone Gel Breast Implants against its benefits.

266. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff have

become liable.

RELIEF REQUESTED

WHEREFORE Plaintiffs pray for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

1) Economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
2) For compensatory damages according to proof;
3) For an award of attorneys' fees and costs;
4) For prejudgment interest and the costs of suit;
5) Punitive or exemplary damages according to proof; and
6) For such other and further relief as this Court may deem just and proper.

Dated: April 25, 2017

By: /s/ Jennifer A. Lenze
Jennifer A. Lenze
Jaime E. Moss
LENZE MOSS, PLC
Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand individual trials by jury as to all claims so triable in this action.

Dated: April 25, 2017

By:/s/ Jennifer A. Lenze
Jennifer A. Lenze
Jaime E. Moss
LENZE MOSS, PLC

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that, on April 25, 2017 a copy of the foregoing **FIRST AMENDED COMPLAINT FOR DAMAGES; DEMAND FOR JURY TRIAL** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

By:/s/ Jennifer A. Lenze
Jennifer A. Lenze